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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,934	10/27/2003	Jacob Richter	2388/46607	2137

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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	**PAPER NUMBER**
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,934	RICHTER ET AL.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32 and 34-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32 and 34-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 May 2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Ritch et al. (Patent No. 5,092,837).

Ritch et al. disclose a method (see entire document) comprising the steps of providing an intraocular implant (for example, see Figure 4D; tube 21, an outlet end having a flange 24, an inlet end located opposite the outlet end, and tube passage 36), providing a delivery device (16, for example, see Figure 4A; comprising a rod-like instrument 34, handles 38, 31, and 32, a tip 35, and an abutment surface, which is the outside surface of tip 35), attaching the implant (21) to the delivery device (16) with the tip (35) of the rod-like instrument (34) penetrating the tube passage (36) of the implant

(column 5, lines 60-63) and the abutment surface (outside surface of tip 35) abutting the flange (since it touches flange 24 along the inside border; see Figure 4B), directing the implant (21) by the delivery device (16) to the implantation site (column 4, line 57), inserting the implant (21) through the sclera (18) at the implantation site (column 6, lines 6-31) such that the inlet end is located within the anterior chamber of the wall (see Figure 4D), and withdrawing the delivery device (column 6, lines 37-40). Figures 4A-4B show the abutment surface (outside surface of tip 35) of the delivery device (16) has an angle generally corresponding to an angle of the flange (24) of the intraocular implant.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 34-36 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. in view of Rubinstein (Patent No. 5,433,701), and further in view of Goldsmith (Patent No. 5,053,040).

Donowitz et al. disclose a method (see entire document) comprising the step of providing an intraocular implant (for example, see Figure 4; tube 28, an inlet end 38, an outlet end opposite the inlet end having a flange 34, and tube passage 30). Donowitz et al. fail to specifically disclose inserting the implant through scleral tissue. However, Donowitz et al. disclose directing the implant to an implantation site, which includes either directly through the cornea or through other areas of the eye (column 4, lines 14-17).

Rubinstein discloses a method (see entire document) comprising the steps providing an intraocular implant (for example, see Figure 2, element 10; having an inlet end 12 with a beveled surface 16, an outlet end 14, and passages 28 and 22), and teaches inserting the intraocular implant (Figure 2, element 10) through scleral tissue at the implantation site such that the inlet end (12) of the implant (10) is located within the anterior chamber of the eyeball (column 7, lines 18-23; Figure 2) and teaches the beveled surface (16) at the inlet end (24) of the implant (10) faces away from the iris (Figure 2, element 21), in order to minimize the possibility that the iris (21) will obstruct the passage of aqueous humor from the anterior chamber of the eye into the tube passageway (22) of the implant (column 3, lines 48-68, through column 4, lines 1-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert the intraocular implant through scleral tissue as taught by Rubinstein in order to further facilitate the removal of aqueous from the anterior chamber of the eye (i.e., without causing hypotonicity), thus reducing intraocular pressure (column 1, lines 54-57 and column 2, lines 30-31). Donowitz et al. in view of Rubinstein fail to disclose

how the implant is delivered, specifically, attaching the implant to a delivery device and directing the implant to the implantation site by the delivery device.

Goldsmith discloses a method of delivering an implant (see entire document) Goldsmith teaches the steps of attaching an implant (12) with a flange (64) to a delivery device (10) comprising a rodlike instrument, wherein the rodlike instrument has an abutment surface (16) for abutting the flange (64) of the implant (the abutment surface has an angle generally corresponding to an angle of the flange in that both have an angle of generally zero degrees), directing the implant (12) by the delivery device (10) to an implantation site, inserting the implant (12), and withdrawing the device (for example, see Figures 6-9). Goldsmith further teaches that using the delivery device described above facilitates placement of an implant by preventing tears or excessive stretching of the incision at the implantation site (for example, see column 2, lines 16-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the implant of Donowitz et al. in view of Rubinstein to a delivery device as taught by Goldsmith in order to be able install the implant without tearing and stretching the incision at the implantation site, resulting in satisfactory positioning of the implant (for example, see column 2, lines 4-21). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the abutment surface of Goldsmith with an angle corresponding to the angle of the flange of the Donowitz in view of Rubinstein implant, since Goldsmith teaches the abutment surface (16) lies flush with the flange (64) of the implant (12; for example, see Figures 6-9).

7. Claims 37-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. in view of Rubinstein in view of Goldsmith as applied to the claims above, and further in view of Wong et al. (Patent No. 5,000,731).

Donowitz et al. disclose a method (see entire document) comprising the step of providing an intraocular implant (for example, see Figure 4; tube 28, an inlet end 38, an outlet end opposite the inlet end having a flange 34, and tube passage 30). Donowitz et al. fail to specifically disclose inserting the implant through scleral tissue. However, Donowitz et al. disclose directing the implant to an implantation site, which includes either directly through the cornea or through other areas of the eye (column 4, lines 14-17).

Rubinstein discloses a method (see entire document) comprising the steps providing an intraocular implant (for example, see Figure 2, element 10; having an inlet end 12 with a beveled surface 16, an outlet end 14, and passages 28 and 22), and teaches inserting the intraocular implant (Figure 2, element 10) through scleral tissue at the implantation site such that the inlet end (12) of the implant (10) is located within the anterior chamber of the eyeball (column 7, lines 18-23; Figure 2) and teaches the beveled surface (16) at the inlet end (24) of the implant (10) faces away from the iris (Figure 2, element 21), in order to minimize the possibility that the iris (21) will obstruct the passage of aqueous humor from the anterior chamber of the eye into the tube passageway (22) of the implant (column 3, lines 48-68, through column 4, lines 1-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert the intraocular implant through scleral tissue as taught by Rubinstein in

order to further facilitate the removal of aqueous from the anterior chamber of the eye (i.e., without causing hypotonicity), thus reducing intraocular pressure (column 1, lines 54-57 and column 2, lines 30-31). Donowitz et al. in view of Rubinstein fail to disclose how the implant is delivered, specifically, attaching the implant to a delivery device and directing the implant to the implantation site by the delivery device.

Goldsmith discloses a method of delivering an implant (see entire document) Goldsmith teaches the steps of attaching an implant (12) with a flange (64) to a delivery device (10) comprising a rodlike instrument, wherein the rodlike instrument has an abutment surface (16) for abutting the flange (64) of the implant (the abutment surface has an angle generally corresponding to an angle of the flange in that both have an angle of generally zero degrees), directing the implant (12) by the delivery device (10) to an implantation site, inserting the implant (12), and withdrawing the device (for example, see Figures 6-9). Goldsmith further teaches that using the delivery device described above facilitates placement of an implant by preventing tears or excessive stretching of the incision at the implantation site (for example, see column 2, lines 16-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the implant of Donowitz et al. in view of Rubinstein to a delivery device as taught by Goldsmith in order to be able install the implant without tearing and stretching the incision at the implantation site, resulting in satisfactory positioning of the implant (for example, see column 2, lines 4-21). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the abutment surface of Goldsmith with an angle corresponding to the angle of the flange of

the Donowitz in view of Rubinstein implant, since Goldsmith teaches the abutment surface (16) lies flush with the flange (64) of the implant (for example, see Figures 6-9). Donowitz in view of Rubinstein in view of Goldsmith fails to disclose the implant has a side opening, or hole, that serves as a marker that is visible upon penetration through scleral tissue.

Wong et al. disclose an implant (see entire document) providing a passage for fluid flow in order to reduce pressure within an organ. Wong et al. teach circumferential holes (13) in order to facilitate fluid drainage (for example, see column 3, lines 43-47). It is obvious that these circumferential holes (13) may be used as "markers" since they are located on the inlet end of the tube, which would be clearly visible on the implant upon penetration through the scleral tissue (see Figure 1 of Donowitz et al. for illustration). Therefore, to construct the implant of Donowitz et al. in view of Rubinstein in view of Goldsmith with markers, such as circumferential holes, as taught by Wong et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to further facilitate fluid drainage.

Response to Arguments

8. Applicant's arguments filed 08 May 2007 have been fully considered but they are not persuasive. Applicant argues primarily that the references do not disclose or suggest each and every element claimed. Examiner respectfully disagrees.

Applicant argues that the abutment surface of the rodlike instrument of Ritch does not have an angle generally corresponding to the angle of the flange of the intraocular implant of Ritch (see claim 32). However, the figures of Ritch clearly show

that the abutment surface defined by the examiner (see above) moves with the flange defined by the examiner (see above), in which both have an angle of generally zero degrees.

9. Applicant's arguments with respect to claims 34-43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9-5:30, Fridays 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
June 15, 2007

(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
6/20/07